

REMARKS

This application has been reviewed in light of the Office Action mailed on June 15, 2006. Claims 1-9 and 12-21 are currently pending in this application with Claims 1 and 12 being in independent form. None of the claims have been amended by this response. In view of the remarks to follow, reconsideration and allowance of this application are respectfully requested.

In the Office Action, Claims 1, 8 and 9 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,797,961 to Smith et al. ("Smith '961") in view of U.S. Patent No. 4,799,484 to Smith ("Smith '484"). In the Office Action, it is asserted that Smith '961 teaches a surgical needle comprising, inter alia, an elongated body defining a longitudinal y-axis; the needled portion having three cutting edges; and a distal shaft transition portion defining a cross section of general triangular character interconnected by rounded surfaces. It is further asserted in the Office Action that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the surgical needle of Smith '961 with an enlarged transition portion adjacent to the central shaft where the x-dimension (height) of this portion is larger than that of the shaft as taught by Smith '484.

Applicants contend that the combination of Smith '961 with Smith '484 is improper. While Smith '961 relates to a cutting edge needle (i.e., needle portion having three sides), Smith '484 relates to a tapered needle. The combination of a cutting edge needle and a tapered needle would compromise or destroy the intended function of both needles, in violation of §103 of the MPEP. Generally, cutting edge needles are used when suturing relatively tough or dense tissue, such as skin, whereas tapered needles are used for penetration of less dense

tissue such as vascular tissue. Also, surgeons use tapered needles to minimize the likelihood of trauma to tissue whereas cutting needles, by their very nature, are less likely to minimize trauma. Specifically, the cutting needles cut and/or incise tissue.

Notwithstanding the improper combination of Smith '961 with Smith '484, Applicants contend that Smith '484 does not disclose an x-dimension (height) of an enlarged transition portion that is larger than that of the shaft portion. Specifically, the height dimension T of Smith '484 "remains constant" from the "jointure of the point and body sections" (see column 3, line 13; column 4, lines 42 and 47).

In addition, Applicants respectfully disagree with the position taken in the Office Action regarding the discussion of Figure 11 in Smith '961 and a possible modification where each of the three sides could contain oblique planar surfaces based on the disclosure of Figure 5D. Figure 11 of Smith '961 is directed to a prior art device where two of the three sides include a pair of intersecting surfaces. Figure 5D of the disclosure relates to an embodiment where the surfaces of the needle are concave. However, contrary to the position taken in the Office Action, one skilled in the art would not be motivated to modify the prior art device of Figure 11 to include a third side with planar surfaces. Moreover, the disclosure of Smith '961 teaches away from the geometry of the prior art device of Figure 11 due to difficulties in manufacturing the intersecting sides 580, 590 (column 5, lines 30-33 of Smith '961). Thus, there would be no suggestion or reason to modify the third side of the prior art device of Figure 11. For at least these reasons, Applicants respectfully request withdrawal of this rejection with respect to Claim 1 and to Claims 8 and 9, which depend therefrom.

With further reference to rejected Claim 9, Applicants also assert that Smith '961 do not disclose a needle having a distal shaft portion defining a cross-section of general triangular character that includes three planar surfaces interconnected by rounded surfaces, as Applicants' claim. Specifically, Smith '961 disclose in column 3, lines 4-8 that the cross-section of central section may be triangular and also disclose a **rectangle** appearing to have its surfaces interconnected by rounded surfaces. However, Smith '961 fails to disclose a distal shaft portion having **triangular** cross-section interconnected by rounded surfaces, as Applicants' claim. Accordingly, for at least this additional reason, Applicants request the withdrawal of this rejection with respect to Claim 9.

In the Office Action, Claims 1, 2, 3, 4 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,030,228 to Wong ("Wong '228") in view of Smith '484 and further in view of U.S. Patent No. 5,403,344 to Allen ("Allen '344"). It is respectfully submitted that the present disclosure as claimed is patentably distinguishable over the combination of Wong '228, Smith '484 and Allen '344. Specifically, as discussed above, Applicants contend that the combination of a cutting edge needle (Wong '228) and a tapered needle (Smith '484) is improper.

In addition, the combination fails to disclose a needle having three sides with "each side including one sole pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side," as recited in Applicants' Claim 1. In the illustrated embodiments of Wong '228, it appears that there are at most two sides of the needle that include a sole pair of planar surface portions (Figs. 5 and 12). The needle of Smith '484, being tapered, does not have any sides that include such a surface, as the needle end portion has a

round cross-section. Additionally, the needle of Allen '344 does not include "**one sole pair** of planar surface portions" on each side. Conversely, Allen '344 discloses a needle where each side includes **five** planar surface portions thereon. Therefore, the combination of Wong '228, Smith '484 and Allen '344 fails to disclose a needle having three sides with "each side including one sole pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side," as recited in Applicants' Claim 1. For at least these reasons, Applicants respectfully request withdrawal of this rejection with respect to Claim 1 and to Claims 2, 3, 4 and 7, which depend therefrom.

With further reference to rejected Claim 3, Applicants also assert that Wong '228, Smith '484 and Allen '344 do not teach or suggest, either alone or in combination, a needle with an enlarged transition portion where both the x-dimension and the z-dimension is greater than corresponding dimensions of the adjacent central shaft. While Smith '484 may disclose a needle portion (12) having a larger width (X_1) than the width (X_2) of intermediate body section (16), the height dimension (T) remains constant (see column 4, lines 46-47, FIGS. 1c, 2c and 3c). Thus, Smith '484 does not disclose a needle with an enlarged transition portion having two dimensions that are greater than corresponding dimensions of an adjacent central shaft, as recited in Claim 3 of Applicants' disclosure. Accordingly, for at least this additional reason, Applicants request the withdrawal of this rejection with respect to Claim 3.

In the Office Action, Claims 1, 5 and 6 were rejected under 35 U.S.C. §103(a) as being unpatentable over Allen '344 in view of Smith '484 and further in view of Wong '228. In Claims 5 and 6, Applicants' claim a needle having three sides and each side includes one **sole** pair of planar surface portions that intersect and form an angle range and an approximate angle at

its intersection. While the angles disclosed in Allen '344 may be in accordance with the assertion in the Office Action, these angles are not formed at the intersection between a sole pair of planar portions, as Applicants claim. For at least this reason and the reasons above, Applicants respectfully request withdrawal of this rejection with respect to Claims 1, 5 and 6.

Claims 12-15 and 18-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,730,732 to Sardelis ("Sardelis '732") in view of Wong '228 and further in view of Allen '344. Sardelis '732 disclose a needle 50 with a distal piercing point 70. The piercing point 70 is three-sided with each side being flat (FIG. 7). It is respectfully submitted that the present disclosure is patentable over the combination of Sardelis '732, Wong '228 and Allen '344. For example, the combination fails to disclose the recited "each [of the three sides] including a pair of planar surface portions arranged in oblique relation and intersecting along a median plane bisecting a respective side to define a general concave appearance," as required by independent Claim 12. With Wong '228, it appears that there are at most two sides of the needle that include a sole pair of planar surface portions (Figs. 5 and 12). With Allen '344, the multi faceted needle includes extended legs which define multiple surfaces none of which intersect along a median plane to define a general concave configuration. Thus, a needle having three sides where each of the three sides including a pair of planar surface portions arranged in oblique relation and intersecting along a median plane bisecting a respective side to define a general concave appearance is not suggested by the combination of Sardelis '732, Wong '228 and Allen '344. Accordingly, withdrawal of this rejection is respectfully requested.

In the Office Action, Claims 1, 16 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Smith '961 in view of Sardelis '732. Smith '961 was discussed

hereinabove and relates to a cutting edge needle. Sardelis '732 relates to a needle piercing point 20 having three flat sides. For at least the reasons discussed above, Applicants' respectfully request withdrawal of this rejection.

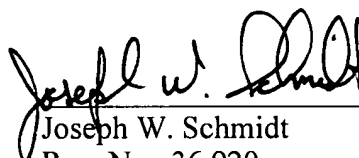
CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that all claims pending in the application, namely Claims 1-9 and 12-21, are in condition for allowance and patentably distinguishable over the art of record.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, she is requested to call the Applicants' undersigned attorney at her convenience.

Respectfully submitted,

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road
Suite 225
Melville, New York 11747
Tel.: (631) 501-5700
Fax: (631) 501-3526



Joseph W. Schmidt
Reg. No. 36,920
Attorney for Applicants

Mailing Address:
Chief Patent Counsel
UNITED STATES SURGICAL
Division of Tyco Healthcare Group LP
195 McDermott Road
North Haven, CT 06473
(203) 492-8193